VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 03/24/09

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Richard Harvie, R. Ph.
Norman Ward, M.D.
Lynne Vezina, R.Ph.
Cheryl Gibson, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Nancy Hogue, Pharm.D. (MHP)
Erin Cody, M.D., OVHA
Stacey Baker, OVHA
Nancy Miner, (MHP)
Robin Farnsworth, OVHA
Judy Jamieson, OVHA

Guests:

Brian Korenda, GSK
Carl Marchand, AstraZeneca
Carl Pepe, GSK
Danielle Moon, Merck
Eileen Mann, GSK
James Kokoszyna, Allergan
Kevin Danielson, Pfizer
Larry Winfield, Novartis
Mark Kaplan, Abbott
Michael Deorsey, Abbott
Michael Difiore, BioGen Idec
Paul Fanikos, BI
Paul Kelly, Janssen
Scott Mosher, GSK
Tracy Wall, Merck

Michael Scovner, M.D. Chair, called the meeting to order at 7:06 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The February 2009 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Legislative Session: No definitive action has occurred yet in the legislature regarding the various proposals that have been made that may impact the Medicaid pharmacy program.

4. Medical Director Update: *Erin Cody, M.D., OVHA*

- Clinical Programs Update: No updates to report.
- Prescriber Comments: No comments to report.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Anti-psychotics: Atypicals and Combinations (Seroquel XR®): Discussion continued regarding the placement of Seroquel XR® on the PDL. Due to the introduction of generic risperidone and its subsequent drop in price, it was recommended that Seroquel XR® remain as PA required.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Alvesco® (ciclesonide) Inhaler: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has been started and stabilized on the medication OR the patient has had a documented side effect, allergy, or treatment failure to at least two preferred inhaled glucocorticoids. A quantity limit of 3 inhalers (80 mcg/inh strength) or 6 inhalers (160 mcg/inh strength) per 90 days was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Nplate® (romiplastim) Injection: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient is at least 18 years of age AND the diagnosis or indication is immune (idiopathic) thrombocytopenic purpura (ITP) AND the patient's platelet count is less than 30,000/µL (<30 x 10^9/L) AND the patient has had a documented side effect, allergy, treatment failure or a contraindication to therapy with glucocorticosteroids. If Nplate® is approved, the proposed length of authorization is 3 months initially and 6 months upon recertification.

Public Comment: No public comment.

Board Decision: The Board chose to defer a decision at this time and requested that input be obtained from a hematologist regarding required treatments that should be tried before approval of the drug. The Board requested that this information be brought back to the May meeting.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- New to Market Drugs:
  Currently, medications that have been on the market for less than 6 months require Prior Authorization. The criteria used by the clinical call center for accessing the PA request at this time are quite non-specific. It was recommended that the criteria for approval be that the medication is being prescribed for an FDA approved indication AND the patient meets age requirements for the medication as approved by the FDA AND therapies currently considered standard of care have been tried with treatment failure, allergy or side effects.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board also recommended that requests for new to market medications that will cost > $ 500.00/month be additionally reviewed by OVHA and that when approvable, fill quantity be limited to a one month supply per fill.

- Cosmetic Drugs/Drugs for Hair Growth: It was recommended that cosmetic uses of drugs not be covered if there is no medical necessity for the medication. This would include, for example, medications FDA approved to reduce wrinkles and to promote hair growth.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

8. Drug Classes – Annual Review:
(Public comment prior to Board action)

Anemia Medications – Erythropoetins: No changes were recommended to the current approval criteria.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

Alzheimer's Medications
- Cholinesterase Inhibitors
- NMDA Receptor Antagonist

No changes were recommended to the current approval criteria for the above 2 categories.

Public Comment: No public comment.

Board Decision: The Board approved leaving the current approval criteria and preferred drugs unchanged.

Migraine – Triptans: No changes were recommended to the current approval criteria for specific drugs. It was recommended to institute criteria for evaluation of requests to exceed the quantity limits specified. It was recommended that in order to approve requests to exceed the monthly quantity limit that the patient must be taking a medication for migraine prophylaxis AND if the patient has more than 15 headaches per month that the patient is being followed by a headache specialist or a neurologist.

Public Comment: Brain Korenda and Carl Pepe – GSK – Discussed the clinical data with Treximet® and possible step therapy requirements.

Board Decision: The Board approved all of the recommendations proposed except did not want to require that the patient see a particular type of physician if experiencing many headaches and requesting to exceed the quantity limit.

Multiple Sclerosis Injectables: No changes were recommended to the current medication category.

Public Comment: Michael Difiore, BioGen Idec – Commented on the role of Tysabri®.

Board Decision: The Board approved leaving the self-injectable products as currently established but did request that additional input be obtained from a neurologist on the role of Tysabri® in rapidly progressing multiple sclerosis at a later meeting.

Parkinson's Medications

- COMT Inhibitors
- Dopamine Precursor/Dopa Decarboxylase Inhibitors
- Dopamine Agonists
- MAO-B Inhibitors
- Other - Stalevo® (carbidopa/levodopa/entacapone)

It was recommended that all subcategories remain as currently established except that Tasmar® should move to PA required due to side effects and safety concerns compared to the other agent in the category. Criteria for approval would be that the diagnosis or indication is Parkinson's disease AND the patient has had a documented side effect, allergy, or treatment failure with Comtan®.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

Skeletal Muscle Relaxants: No changes are recommended to the current approval criteria with the exception that the combination product of ophenadrine/ASA/caffeine should be moved to PA required with the criteria for approval being that the prescriber must provide a clinically valid reason why generic orphenadrine in combination with aspirin (or another analgesic) cannot be used. The category was also subdivided into single agent and combination products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

Urinary Antispasmodics: It was recommended that generic oxybutynin XL move to PA required after clinical criteria are met due to its higher net cost to the state Medicaid program. It was also recommended that a mailing be sent to prescribers of oxybutynin XL and Detrol LA® requesting that they move their patients to one of the preferred products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Desmopressin: The prior-authorization program for desmopressin nasal spray was implemented on 5/1/2008. A review of utilization data showed a decrease in the average number of unique utilizers, paid claims and the total cost by 54% (13 to 6), 57% (14 to 5), and 45% ($2,240.49 to $1,233.06), respectively, following the PA program implementation. After reviewing the 20 desmopressin nasal spray prior authorization requests and utilization data, it has been concluded that the current prior authorization criteria is appropriate. The utilization and cost of the desmopressin tablets remained

relatively consistent throughout the reviewed time period. However, while an average cost per claim for the generic desmopressin tablets was noted to be $138.71, the brand desmopressin tablets cost the plan $1,165.15 per each paid claim. Switching the 35 patients currently maintained on an oral desmopressin brand to a generic formulation could result in a cost savings of $35,925.46.
Based on the utilization of the desmopressin tablets, it is recommended that all branded tablets be placed on prior authorization with the criteria for approval being that the patient is being treated for 1.) Diabetes Insipidus and/or 2.) Primary nocturnal enuresis AND the patient has had a documented intolerance to generic desmopressin tablets.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Migraine/Triptans: Users of triptans who averaged more than 8 units a month for 6 months (July 2008 – Jan 2009) were evaluated to see if they were also receiving migraine prophylaxis therapy. Of the 109 members identified, 68 patients were on prophylactic treatment while 41 were not. It was recommended that a mailing that would include national guidelines be sent to the prescribers of triptan therapy for the members who were receiving large quantities of triptans with no migraine prophylactic therapy identified. Prescribers would be asked to consider prescribing prophylactic therapy and to complete a response form.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

10. New Drug Product Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 01/24/09 - 02/27/09. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*
FDA Safety Alerts

- Raptiva® - PML: The FDA issued a Public Health Advisory to notify healthcare professionals of three confirmed, and one possible report of progressive multifocal leukoencephalopathy (PML), a rare brain infection, in patients using the psoriasis drug Raptiva. The agency will take appropriate steps to ensure that the risks of Raptiva do not outweigh its benefits, that patients prescribed Raptiva are clearly informed of the signs and symptoms of PML, and that health care professionals carefully monitor patients for the possible development of PML. It was recommended that the information be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- Zonisamide – metabolic acidosis: The FDA notified healthcare professionals that updated clinical data has determined that treatment with zonisamide, indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy, can cause metabolic acidosis in some patients. Patients with predisposing conditions or therapies may be at greater risk for developing metabolic acidosis and the risk of zonisamide-induced metabolic acidosis appears to be more frequent and severe in younger patients. FDA recommends that healthcare professionals measure serum bicarbonate before starting treatment and periodically during treatment with zonisamide. It was recommended that the information be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- Metoclopramide – tardive dyskinesia: The FDA notified healthcare professionals that manufacturers of metoclopramide, a drug used to treat gastrointestinal disorders, must add a boxed warning to their drug labels about the risk of its long-term or high-dose use. Chronic use of metoclopramide has been linked to tardive dyskinesia, which may include involuntary and repetitive movements of the body, even after the drugs are no longer taken. These symptoms are rarely reversible and there is no known treatment. It was recommended that the information be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: None needed.

- Risk Evaluation for Opioids: The US Food and Drug Administration (FDA) announced that they have contacted the manufacturers of opioid pain medications, including fentanyl, morphine, and oxycodone, requiring them to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of these drugs outweigh the risks. Letters went out February 6 to 16 manufacturers of 24 brand-name and generic products with either approved new drug applications (NDAs) or approved abbreviated NDAs, most of them extended-release products or transdermal systems. This was presented as information only, no action is recommended.

Public Comment: No public comment.

Board Decision: None needed.

13. <u>Adjourn</u>: Meeting adjourned at 8:26 p.m.

Next DUR Board Meeting
Tuesday, May 12, 2009
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.